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PENDING CLAIMS IN STK-071 CPA2
(USSN 08/822,186)

1. (Seven Times Amended) A device for inducing local bone or cartilage formation, comprising:

a purified osteogenic protein capable of inducing repair of endochondral bone, or cartilage, chondral, or osteochondral defects, said purified osteogenic protein being isolated from naturally-occurring sources or produced by recombinant DNA techniques;

a matrix; and

a binding agent selected from the group consisting of mannitol, dextran, cellulose, white petrolatum, and derivatives thereof;

wherein the device does not comprise a synthetic polymer matrix or a demineralized bone matrix, and said binding agent has a viscosity of about 10-200 cP or a degree of substitution of 0.65-0.90.

2. (Thrice Amended) The device of claim 1, wherein said osteogenic protein is selected from the group consisting of: OP1, OP2, OP3, BMP2, BMP3, BMP4, BMP5, BMP6, BMP9, BMP10, BMP11, BMP12, BMP15, BMP16, DPP, Vgl, 60A protein, GDF-1, GDF3, GDF5, GDF6, GDF7, GDF8, GDF9, GDF10, GDF11, and variants thereof having conservative amino acid substitutions and substantially similar osteogenic activity.

3. (Thrice Amended) The device of claim 1, wherein said osteogenic protein is selected from the group

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consisting of OP1, OP2, BMP2, BMP4, BMP5, BMP6, and variants thereof having conservative amino acid substitutions and substantially similar osteogenic activity.

4. (Twice Amended) The device of claim 1, wherein said osteogenic protein comprises an amino acid sequence having at least 70% homology with the C-terminal 102-106 amino acids, including the conserved seven cysteine domain, of human OP1, said osteogenic protein capable of inducing repair of endochondral bone when implanted together with a matrix in a mammal.

5. The device of claim 1 wherein said osteogenic protein is OP-1.

6. The device of claim 1 wherein said device comprises at least two different osteogenic proteins.

7. (Amended) The device of claim 1, wherein said matrix is selected from the group consisting of: collagen, apatites, hydroxyapatites, tricalcium phosphates, and admixtures thereof.

8. The device of claim 1 wherein said matrix is collagen.

9. The device of claim 1 wherein said device comprises at least two different matrix materials.

11. The device of claim 1 wherein said binding agent is selected from the group consisting of alkylcelluloses.

12. The device of claim 1 wherein said binding agent is selected from the group consisting of methylcellulose, methylhydroxyethylcellulose, hydroxyethylcellulose, hydroxypropylmethylcellulose, carboxymethylcellulose, sodium carboxymethylcellulose, hydroxyalkylcelluloses, and admixtures thereof.

13. The device of claim 1 wherein said binding agent is carboxymethylcellulose or the sodium salt thereof.

14. The device of claim 1 wherein said device comprises at least two different binding agents.

15. The device of claim 1 further comprising a wetting agent.

16. The device of claim 15 wherein said wetting agent is saline.

17. (Four Times Amended) A device for inducing local bone or cartilage formation, comprising at least approximately 1.25 mg of purified OP-1 and at least approximately 180 mg of carboxymethylcellulose per 1000mg of collagen matrix, wherein said purified OP-1 is isolated from naturally-occurring sources or produced by recombinant DNA

techniques, and said carboxymethylcellulose has a viscosity of about 10-200 cP or a degree of substitution of 0.65-0.90.


18. (Amended) The device of claim 17 comprising at least approximately 2.5 mg of OP-1 per 1000 mg of collagen matrix.

19. (Amended) The device of claim 17 or 18 comprising at least approximately 200 mg of carboxymethylcellulose per 1000 mg of collagen matrix.

20. (Six Times Amended) A device for inducing local cartilage or bone formation comprising a purified osteogenic protein capable of inducing repair of endochondral bone, or cartilage, chondral, or osteochondral defects and a carrier, wherein said carrier comprises one part binding agent and 10 or fewer parts (w/w) matrix, [and] said purified osteogenic protein is isolated from naturally-occurring sources or produced by recombinant DNA techniques, and said binding agent has a viscosity of about 10-200 cP or a degree of substitution of 0.65-0.90.

21. (Twice Amended) The device of claim 20 wherein said carrier comprises one part binding agent and 5 parts (w/w) matrix.

22. (Amended) The device of claim 20 wherein said carrier comprises fewer than 5 parts (w/w) matrix.



23. (Six Times Amended) A device for inducing local bone or cartilage formation comprising a purified osteogenic protein capable of inducing repair of endochondral bone, or cartilage, chondral, or osteochondral defects and a carrier, wherein said carrier comprises 10 or fewer parts (w/w) binding agent and 1 part matrix, [and] said purified osteogenic protein being isolated from naturally-occurring sources or produced by recombinant DNA techniques, and said binding agent has a viscosity of about 10-200 cP or a degree of substitution of 0.65-0.90.

24. (Amended) The device of claim 23 wherein said carrier comprises fewer than 10 parts (w/w) binding agent.

25. The device of claim 17, 18 or 19 further comprising saline.

31. (Three Times Amended) A device for inducing local bone or cartilage formation comprising:
purified OP-1;
collagen matrix; and
carboxymethylcellulose;
wherein said purified OP-1 is isolated from naturally-occurring sources or produced by recombinant DNA techniques, and said carboxymethylcellulose has a viscosity of about 10-200 cP or a degree of substitution of 0.65-0.90.

32. (Twice Amended) A kit for inducing local bone or cartilage

formation using the device of claim 1, the kit comprising:

- (a) a receptacle adapted to house the osteogenic protein and the matrix material, and
- (b) a receptacle adapted to house the binding agent,

wherein the osteogenic protein and matrix material are provided in the receptacle of part (a), and the binding agent is provided in the receptacle of part (b), and said binding agent has a viscosity of about 10-200 cP or a degree of substitution of 0.65-0.90.

33. The kit of claim 32 further comprising a receptacle adapted to house a wetting agent.

35. (Twice Amended) A kit for inducing local bone or cartilage formation using the device of claim 1, the kit comprising:

a first receptacle adapted to house the osteogenic protein, the matrix material, and the binding agent,

wherein the osteogenic protein, matrix material and binding agent are provided in said receptacle, and said binding agent has a viscosity of about 10-200 cP or a degree of substitution of 0.65-0.90.

36. The kit of claim 35, further comprising a second receptacle adapted to house a wetting agent.